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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/879,827 06/20/97 JOFUKU

K 023070067210

002292 HM12/0511
BIRCH STEWART KOLASCH & BIRCH
P O BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER

MOSHER, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

05/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/879,827

Applicant(s)

Jofuku et al

Examiner

Mosher

Group Art Unit

1641



☒ Responsive to communication(s) filed on 10/19/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-37, 40, 41, and 45-109 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4, 6-14, 16-25, 27-35, 37, 40, and 45 is/are rejected.

☒ Claim(s) 5, 15, 26, 36, 41, and 46-109 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641, Examiner Mosher.

The final status of rejection, made in the last Office action, is withdrawn in order to present a rejection of the claims in terms consistent with the recently issued Revised Written Description Guidelines and associated training materials. Additional new double patenting rejections are also included, involving applications filed later than this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-14, 16-25, 27-35, 37, 40, 45, 111-114 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, based upon the revised Interim Written Description guidelines published in the Federal Register on December 21, 1999, (and 1231 OG 123, February 29, 2000) and on the associated training materials which are available on the Internet at

<http://www.uspto.gov/web/offices/pac/writtendesc.pdf>

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A review of the language of the claims indicates that these claims involve a genus of nucleic acids, i.e., any nucleic acid that minimally contains a certain degree of homology with SEQ ID NO: 4 or SEQ ID NO:5, and encodes a polypeptide with the functional attribute of modulating seed mass or oil content. The genus includes any full length gene which contains the sequence, any fusion constructs or cDNAs.

There is a working example involving a single species that is within the scope of the claimed genus, which demonstrably possesses both the structural and the functional characteristics recited in the claim. The working example demonstrating function uses a nucleic acid encoding the AP2 protein, a protein of about 432 amino acids. This protein does comprise the 67 amino acid sequence of SEQ ID NO:4, and the 68 amino acid sequence of SEQ ID NO:5. The specification also discloses additional species that possess the required structural characteristics (SEQ ID Nos. 3, 100-111). These additional species have not been demonstrated to possess the required function.

The domains SEQ ID NO:4 and SEQ ID NO:5 are disclosed as having structures that are theoretically capable of forming amphipathic alpha helical structures that may participate in protein-protein interactions. However, a wide variety of regulatory proteins share some similarity in the structure of a domain, but act upon very different genes and have very different biological effects. For example, the review by Sharrocks et al (Int. J. Biochem. Cell. Biol. 29:1371-1387, 1997) illustrates that a family of transcription factors, ETS, may share similarity in structure of one or more domains, but regulate processes as different as metamorphosis, eye development, and

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oogenesis in insects; hematopoiesis, myeloid & B-cell specific gene expression, neuronal function, and tumorigenesis in mammals. Therefore, in the absence of evidence that the domain structure of SEQ 4 and SEQ 5 confers the required function, one skilled in the art would have reason to doubt that 35%, 60%, or 95% of the domain would confer the required function. One skilled in the art would have reasons to doubt that a protein sharing only 24 amino acids with the 430-amino acid AP2 protein would share the AP2 function of modulating seed mass or oil content. The structural feature which renders the protein recognizable as a DNA-binding protein does not convey the to the artisan any information on the biological function of the protein, since the identity and function of the target gene regulated by the protein cannot be guessed from the structure of the protein, at the current time. Therefore, even if the minimal required structure conferred a DNA-binding activity, the DNA-binding activity would be unlikely to mediate the same biological function, that of modulating seed mass or oil content.

Therefore, although the claim sets forth a necessary common structural attribute for the nucleic acids, there is no evidence that the necessary function is conferred by that structure.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO:4 and 5 are only fragments of any full-length gene product or cDNA species. When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any

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necessary common attributes or features. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus of, e.g., "A cDNA comprising [a partial sequence]," encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. Further, defining "the" cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Here, the specification discloses a number of species that share the common structural feature required for members of the claimed genus, which may or may not share the required functional feature. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fusion proteins, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of Seq 1, 100-111 does not provide an adequate description of the claimed genus "comprising" the recited structure and function.

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Weighing all factors, 1) partial structure of the DNAs that comprise the recited SEQ ID Nos and fragments, 2) the breadth of the claim as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise nucleic acids comprising a domain which is at least 35% (or 60%, or 95%) identical to SEQ ID NO:4 or SEQ ID NO:5, and which encodes a polypeptide that modulates seed mass or oil content. Therefore the genus of nucleic acids clearly embraces species with substantial variation. Because the required genus of materials does have substantial variation, and because possession of the required common structure does not necessarily convey possession of the required function, it is concluded that description of one single functional species is not representative of the gamut of functional members of the genus, and is insufficient to support the invention as broadly claimed.

The following additional reviews (not prior art) are cited as of interest, as further documenting the diverse biological properties of proteins with conserved structural domains:

Riechmann et al, "The AP2/EREB family of plant transcription factors", Biological Chemistry 379:156-29, 1998

Riechmann et al, "MADS domain proteins in plant development", Biological Chemistry 378:1079-1101, 1997

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Clarke et al, "Zinc fingers in *Caenorhabditis elegans*: finding families and probing pathways", Science 282:2018-2022, 1998.

Double Patenting

Claims 1-37, 40, 41, and 45-110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of recently issued U.S. Patent No. 5994,622, for the same reasons as the provisional rejection of 08/700,152 in previous Office actions.

Claims 1-4, 6-14, 16-25, 27-35, 37, 40, 45, 111-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 1 2 4 6-9 12-17 19 20 25-34 36-44 46-52 54 55 57 58 60-69 of copending Application No.08/912,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims are species within instant broader claims. .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 6-14, 16-25, 27-35, 37, 40, 45, 111-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 9-17, 22-31, 36-44, 51, 52, 57, 58 of copending Application No. 09/026,039. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims overlap in scope with the instant claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 5, 36, and 41 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9, 48, and 56 of copending Application No. 09/242,646. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-4, 6-35, 37, 40, and 45-109 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10-47, 49-55, 57 and 58 of copending Application No. 09/242,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap substantially in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 5, 15, 26, 36, 41, and 46-110 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and if double patenting issues are resolved

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The

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examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 10, 2000

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600